1.0 Introduction

William Beaumont Hospital (Beaumont) operates four (4) ethylene oxide (EtO) medical sterilizers at the Royal Oak Hospital in Royal Oak, Oakland County, Michigan. The Michigan Department of Environment, Great Lakes and Energy – Air Quality Division (EGLE-AQD) has issued to Beaumont a Renewable Operating Permit (MI-ROP-G5067-2019) for operation of the emission units at the facility. The medical sterilizing equipment covered under the permit consists of:

- Two (2) 3M Steri-Vac 8XL gas sterilizers, identified as EU-ETOSTERILIZER1 and EU-ETOSTERILIZER2, each controlled by an individual dedicated Advanced Air Technologies Safe-Cell Model 2002 acid scrubber and dry bed chemical filter.

- Two (2) 3M Steri-Vac 5XL gas sterilizers, identified as EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4, each controlled by the same, single, Advanced Air Technologies Safe-Cell Model 2002 acid scrubber and dry bed chemical filter.

The hospital refers to EU-ETOSTERILIZER3 as Unit 7A and EU-ETOSTERILIZER4 as Unit 8A.

Air emission compliance testing was performed pursuant to MI-ROP-G5067-2019. Conditions of the ROP state:

1. *The permittee shall verify the EtO destruction efficiency of the acid scrubber and dry bed chemical filter system connected to the vents for EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4 by testing at the owner's expense, in accordance with the Department requirements no later than May 30, 2020. Testing shall be performed using an approved EPA Method listed in 40 CFR Part 60, Appendix A. An alternate method, or a modification to the*

The compliance testing presented in this report was performed by Prism Analytical Technologies, Inc. (PATI) and Impact Compliance and Testing, Inc. (ICT), a Michigan-based environmental consulting and testing company. PATI representative Mr. Trevor Tillman and ICT representative Andrew Rusnak performed the field sampling and measurements January 5 - 6, 2021. Ms. Regina Angellotti of EGLE was onsite to observe portions of the testing. Ms. Kerry Kelly of EGLE video conferenced during each test period to observe portions of the testing.

The emission performance tests consisted of triplicate sampling periods for EtO. Exhaust gas velocity, moisture, oxygen (O_2) content, and carbon dioxide (CO_2) content were determined for each test period to calculate pollutant mass emission rates.

The exhaust gas sampling and analysis was performed using procedures specified in the Test Plan dated April 2, 2020 that was reviewed and approved by the EGLE-AQD. Testing was postponed until January 5 – 6, 2021 due to the COVID-19 pandemic. The postponement was approved by EGLE. Three (3) individual test periods were originally planned to be performed while each sterilizer (EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4) operated and exhausted to the control device independently. During

the test program EGLE representatives indicated that it was their intention that both sterilizers operate and exhaust to the control device simultaneously. Therefore, three (3) emission tests were performed while one sterilizer exhausted to the control device and three (3) emission tests were performed while both sterilizers exhausted to the control device, simultaneously.

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2.0 Summary of Test Results and Operating Conditions

2.1 Purpose and Objective of the Tests

Conditions of MI-ROP-G5067-2019 require Beaumont to test the EtO destruction efficiency of the control device associated with EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4.

2.2 Operating Conditions During the Compliance Tests

Each sterilization cycle is broken down into the following phases:

1. Air removal – Chamber is evacuated to a pressure of approximately 200 mBar. Under a normal cycle this phase has a duration of approximately 10 minutes.
2. Conditioning – Chamber is heated to approximately 55 °C, relative humidity is increased to at least 35% and the chamber is evacuated to a pressure of approximately 120 mBar. Under a normal cycle this phase has a duration of approximately 50 minutes.
3. EtO Inject – EtO canister is punctured and EtO gas is transferred from the canister to the sterilization chamber. Canister is completely emptied within 75 seconds.
4. EtO Expose – Sterilizer chamber is exposed to EtO gas. Under a normal cycle this phase has a duration of approximately 60 minutes.
5. EtO Removal – Initial removal of EtO from chamber to control device, chamber is evacuated to a pressure of 140 mBar. Under a normal cycle this phase has a duration of approximately 15 minutes.
6. Purge – Fresh air is introduced to the chamber, which is held under a slight vacuum (approximately 915 mBar), and exhausted to the control device. Under a normal cycle this phase has a duration of approximately 30 minutes.
7. Aeration – Fresh air is continually introduced to the chamber, which is held under a slight vacuum (approximately 915 mBar), and continually exhausted to the control device. Under a normal cycle this phase has a duration of approximately 12 hours.

EtO is exhausted from the medical sterilizers to the control device during the EtO Removal, Purge and Aeration phases (12.75 hrs total time under a normal cycle).

For the emission testing the sterilizers were put into a special cycle which shortened the Conditioning phase to 5 minutes and EtO Expose phase to 30 seconds. This was done to shorten the time in between test runs. Since EtO is not exhausted during these times it was not expected to affect the measured EtO emission rate. Each test run began when the EtO Removal phase began and continued until one (1) hour of Aeration was completed. This is considered to be the time frame with the highest potential EtO emission rate. The measured emission rate (lb/hr) for this time period was applied to the entire time period that a normal cycle would potentially exhaust EtO (approximately 12.75 hours) to determine the maximum potential, worst-case EtO mass emissions for a normal cycle.

The scrubber tower acid recirculation flowrate (gpm) and exhaust stack airflow meter were recorded in 15-minute increments for each test period. The scrubber acid solution pH was also measured at the beginning of each test run.

Appendix 2 provides operating records for the test periods.

Table 2.1 presents a summary of the average operating conditions during the test periods.

2.3 Summary of Air Pollutant Sampling Results

The gases exhausted from the sampled control device for the medical sterilizers (EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4) were sampled for three (3) one-hour test periods while one medical sterilizer was in operation and three (3) one-hour test periods while two (2) medical sterilizers were in operation. The compliance testing was performed January 5 – 6, 2021.

Table 2.2 presents the average measured EtO emission rates and destruction efficiencies for each operating scenario (average of the three test periods).

Test results for each one-hour sampling period and comparison to the permitted emission rates are presented in Section 6.0 of this report.

Table 2.1 Average operating conditions during the test periods

Parameter	EU-ETOSTERILIZER3 OPERATION	EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4 OPERATION
Column A Recirculation Rate (gpm)	3.7	3.7
Column B Recirculation Rate (gpm)	3.3	3.3
Duct Airflow Monitor (inH2O)	3.3	3.3
Scrubber Acid pH	1	1

Table 2.2 Average measured emission rates and destruction efficiency of each operating scenario (three-test average)

Emission Unit / Operating Scenario	EtO Injected (lb)	Maximum Potential EtO Exhausted Per Cycle (lb)	EtO Destruction Efficiency (%)
EU-ETOSTERILIZER3	0.22	0.00025	99.9
EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4	0.44	0.00035	99.9
Permit Limit	-	-	***99.5***

3.0 Source and Sampling Location Description

3.1 General Process Description

Two (2) identical EtO medical sterilizers, EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4 were sampled during the emission test program. The units were manufactured by 3M and are Steri-Vac 5XL gas sterilizers.

Each sterilization cycle/load is run as a batch process. The medical equipment is loaded into the medical sterilizer. The sterilizer is closed and locked and EtO gas is injected into the sterilization chamber. After exposure the sterilization chamber is exhausted/aerated.

3.2 Rated Capacities and Air Emission Controls

The medical sterilizers use EtO gas to sterilize medical equipment. EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4 each use 0.22 lb EtO/cycle. The EtO is contained in individual cartridges that are inserted into the medical sterilizer prior to sterilizing each load.

The two (2) sterilizers exhaust to a single Advanced Air Technologies Safe-Cell Model 2002 acid scrubber and dry bed chemical filter control device for EtO control.

3.3 Sampling Locations

The control device exhaust gas is released to the atmosphere through a dedicated vertical exhaust stack with a vertical release point.

Sample ports were installed in the exhaust duct work in the room where the sterilizers are installed. The exhaust velocity sampling ports are located in a duct with an inner diameter of 6.0 inches. The stack is equipped with two (2) sample ports, opposed 90°, that provide a sampling location 38.0 inches (6.3 duct diameters) upstream and 16.0 inches (2.7 duct diameters) downstream from any flow disturbance. In stack concentrations of EtO were extracted from the exhaust duct from a port located more than 8.0 diameters upstream of the velocity sampling ports.

All sample port locations satisfy the USEPA Method 1 criteria for a representative sample location. Individual traverse points were determined in accordance with USEPA Method 1.

Appendix 1 provides diagrams of the emission test sampling locations.

4.0 Sampling and Analytical Procedures

A test protocol for the air emission testing was reviewed and approved by the EGLE-AQD. This section provides a summary of the sampling and analytical procedures that were used during the testing periods.

4.1 Summary of Sampling Methods

USEPA Method 1	Exhaust gas velocity measurement locations were determined based on the physical stack arrangement and requirements in USEPA Method 1
USEPA Method 2	Exhaust gas velocity pressure was determined using a Standard Pitot tube connected to a red oil incline manometer; temperature was measured using a K-type thermocouple connected to the Pitot tube.
USEPA Method 3	Exhaust gas O_2 and CO_2 content was determined using Fyrite gas scrubbers.
USEPA Method 4	Exhaust gas moisture concentration was determined using dry bulb / wet bulb temperature measurements.
ASTM Method D6348	Exhaust gas EtO and moisture content was determined using a FTIR analyzer

4.2 Exhaust Gas Velocity Determination (USEPA Method 2)

The exhaust stack gas velocities and volumetric flow rates were determined using USEPA Method 2 during each test period. A standard Pitot tube connected to a red-oil manometer was used to determine velocity pressure at each traverse point across the stack cross section. Gas temperature was measured using a K-type thermocouple. The Pitot tube and connective tubing were leak-checked periodically throughout the test periods to verify the integrity of the measurement system.

Appendix 3 provides exhaust gas flowrate calculations and field data sheets.

4.3 Exhaust Gas Molecular Weight Determination (USEPA Method 3)

CO_2 and O_2 content in the exhaust gas stream was determined during each test period in accordance with USEPA Method 3. The O2 and CO2 concentrations were verified using Fyrite® gas scrubbers. A grab sample of the medical sterilizer exhaust gas was passed through the scrubbing solutions and the O2 and CO2 concentration of the gas stream was recorded.

Appendix 3 provides O_2 and CO_2 data sheets.

4.4 Moisture Concentration Measurements (USEPA Methods 4)

Moisture content of the EtO medical sterilizer exhaust gas is similar to ambient air. The EtO medical sterilizer exhaust gas temperature was less than 100 °F. Moisture content of the EtO medical sterilizer exhaust gas was determined using the Method 4 wet bulb/dry bulb temperature approximation method. One reading was performed in conjunction with each velocity traverse.

Appendix 4 provides moisture calculation sheets.

4.5 Measurement of EtO and Moisture via FTIR (ASTM D6348)

Ethylene oxide and moisture concentration in the exhaust gas stream was determined using an MKS Multi-Gas 2030 Fourier transform infrared (FTIR) spectrometer in accordance with test method ASTM D6348. The FTIR was equipped with StarBoost in order to measure low level EtO concentrations.

Samples of the exhaust gas were delivered directly to the instrumental analyzer using a Teflon® heated sample line to prevent condensation. The sample to the FTIR analyzer was not conditioned to remove moisture. Therefore, measurements correspond to standard conditions with no moisture correction (wet basis).

A calibration transfer standard (CTS), methane standard, and nitrogen zero gas were analyzed before and after each test run. Analyte spiking with ethylene oxide was performed to verify the ability of the sampling system to quantitatively deliver a sample containing the compound of interest from the base of the probe to the FTIR. Data was collected at 0.5 cm-1 resolution. Instrument response was recorded using MG2000 data acquisition software.

Appendix 5 provides EtO calculation sheets. Raw instrument response data for the FTIR analyzer is provided in Appendix 6.

4.6 EtO Destruction Efficiency

Exhaust gas volumetric flowrate and molecular weight were measured to calculate the EtO mass emission rate (pounds per hour). The maximum potential amount of EtO exhausted from the control device was determined multiplying the EtO mass emission rate during the first hour (maximum EtO exhaust rate) by the total EtO exhaust cycle time (12.75 hrs). The amount of EtO injected into the medical sterilizer (lb) was determined using a calibrated scale and taking pre and post weights of the individual EtO canisters. Comparison of the mass of EtO injected into the medical sterilizer and the mass of EtO exhausted from the control device was used to determine the destruction efficiency of the control device.

EtO destruction efficiency was determined based on the ratio of the inlet and outlet EtO mass flowrate:

$$\text{EtO DE} = [1 - (M_{EtO,out} / M_{EtO,in})] \times 100\%$$

5.0 QA/QC Activities

5.1 Flow Measurement Equipment

Prior to arriving onsite, the instruments used during the source test to measure exhaust gas properties and velocity (barometer and Pitot tube) were calibrated to specifications in the sampling methods.

5.2 Scale Calibration

The scale used to weigh the EtO canister pre and post test was calibrated each day using NIST traceable weights.

5.3 FTIR QA/QC Activities

At the beginning of each day a calibration transfer standard (CTS, methane gas), analyte of interest (EtO) and nitrogen calibration gas was directly injected into the FTIR to evaluate the unit response.

Prior to and after each test run the CTS was analyzed. The methane was passed through the entire system (system purge) to verify the sampling system response and to ensure that the sampling system remained leak-free at the stack location. Nitrogen was also passed through the sampling system to ensure the system is free of contaminants.

Analyte spiking, of the emission unit, with EtO was performed to verify the ability of the sampling system to quantitatively deliver a sample containing the compound of interest from the base of the probe to the FTIR and assure the ability of the FTIR to quantify that compound in the presence of effluent gas.

As part of the data validation procedure, reference spectra were manually fit to that of the sample spectra (two spectra from each test period) and a concentration was determined. Concentration data was manually validated.

Appendix 6 presents test equipment quality assurance data (Pitot tube, barometer and scale calibration records).

6.0 Results

6.1 Test Results and Allowable Emission Limits

Operating data and air pollutant emission measurement results for each one-hour test period are presented in Tables 6.1 – 6.2.

The control device used to control emissions from EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4 has a minimum required EtO destruction efficiency of 99.5% specified in MI-ROP-G5067-2019.

The measured EtO destruction efficiency of the control device when one sterilizer was in operation was 99.9%. The measured EtO destruction efficiency of the control device when two sterilizers were in operation was 99.9%.

6.2 Variations from Normal Sampling Procedures or Operating Conditions

The testing for all pollutants was performed in accordance with specified methods and the approved test protocol. The sterilizers were operated in a special cycle which reduced the time spent in the preconditioning and exposure phases (phases where EtO is not exhausted from the unit). The special cycle used the same amount of EtO as a normal cycle and had a similar EtO exhaust phase. The test results indicated a passing result after one-hour, therefore, the aeration cycle was stopped after one-hour as detailed in the test protocol.

Three (3) minutes (11:09 – 11:11 on 1/6/21) of data was removed from the third test period performed while two sterilizers were exhausting to the control device because nitrogen calibration gas was injected into the FTIR.

Table 6.1 Measured control device exhaust gas conditions and air pollutant emission rates for operation of one sterilizer (EU-ETOSTERILIZER3)

Test No. Test date Test period (24-hr clock)	1 1/5/21 858-958	2 1/5/21 1025-1139	3 1/5/21 1202-1315	Three Test Average
Pump A flowrate (gpm)	3.7	3.7	3.7	3.7
Pump B flowrate (gpm)	3.3	3.3	3.3	3.3
Duct air flowrate (inH_2O)	3.3	3.3	3.3	3.3
Scrubber acid pH	1	1	1	1
Exhaust Gas Composition				
CO_2 content (% vol)	0.0	0.0	0.0	0.0
O_2 content (% vol)	21.0	21.0	21.0	21.0
Moisture (% vol)	0.54	0.57	0.57	0.56
Exhaust gas flowrate (scfm)	197	194	191	194
Ethylene Oxide Injected				
Canister Preweight (g)	126.374	125.952	125.517	125.948
Canister Postweight (g)	27.088	26.856	26.833	26.926
EtO Injected (lb)	0.22	0.22	0.22	0.22
Ethylene Oxide Exhausted				
EtO conc. (ppbv)	10	16	19	15
EtO emissions (lb/hr)	1.35E-05	2.13E-05	2.50E-05	1.99E-05
EtO emitted/cycle (lb)	1.73E-04	2.72E-04	3.18E-04	2.54E-04
Destruction Efficiency				
EtO DE (%)	99.9	99.9	99.9	99.9
Permit Limit (%)	-	-	-	*99.5*

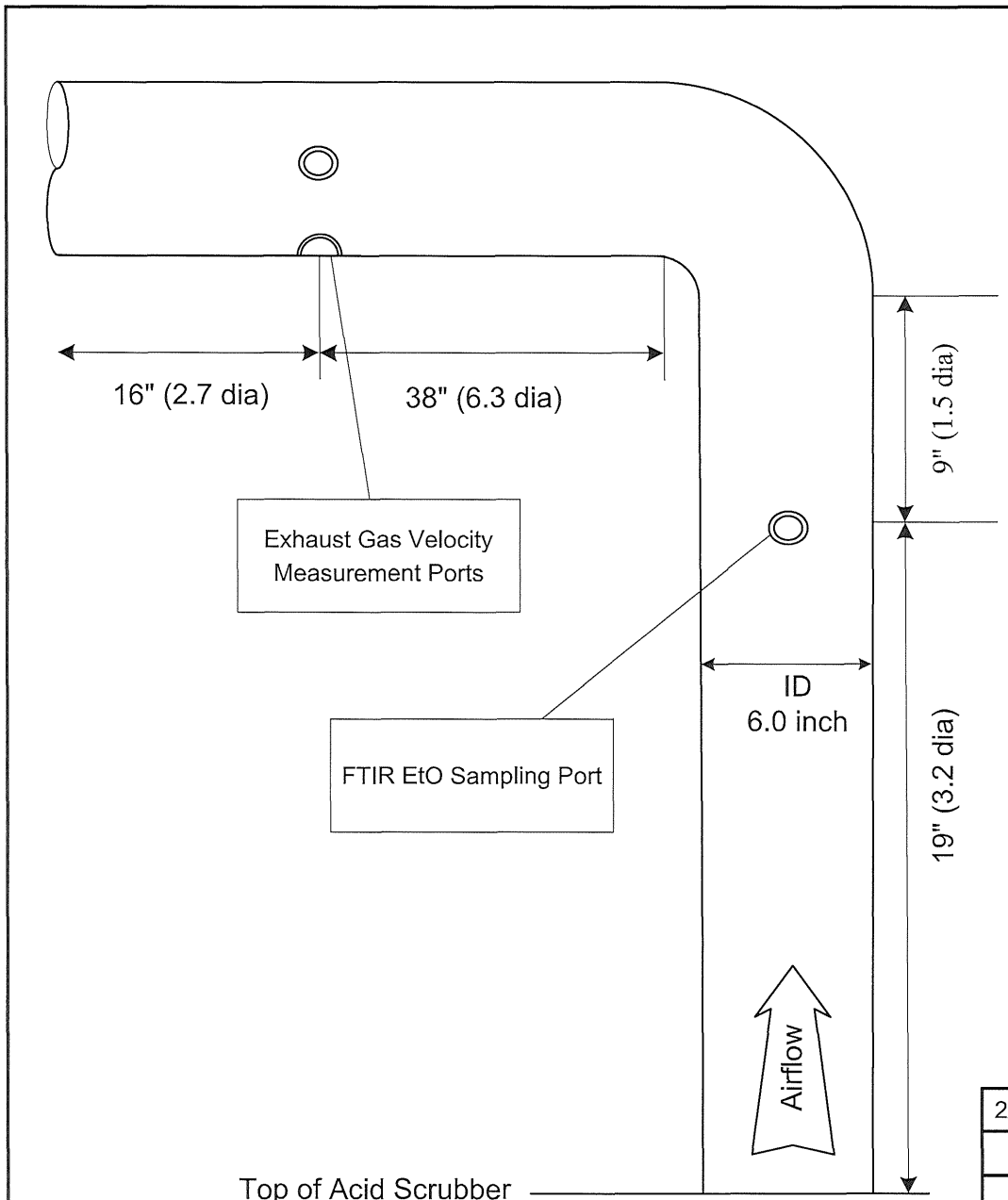
Table 6.2 Measured control device exhaust gas conditions and air pollutant emission rates for operation of two sterilizers (EU-ETOSTERILIZER3 and EU-ETOSTERILIZER4)

Test No. Test date Test period (24-hr clock)	1 1/6/21 751-905	2 1/6/21 930-1048	3 1/6/21 1105-1223	Three Test Average
Pump A flowrate (gpm)	3.7	3.7	3.8	3.7
Pump B flowrate (gpm)	3.3	3.3	3.3	3.3
Duct air flowrate (inH_2O)	3.3	3.3	3.3	3.3
Scrubber acid pH	1	1	1	1
Exhaust Gas Composition				
CO_2 content (% vol)	0.0	0.0	0.0	0.0
O_2 content (% vol)	21.0	21.0	21.0	21.0
Moisture (% vol)	0.61	0.63	0.64	0.63
Exhaust gas flowrate (scfm)	198	198	190	195
Ethylene Oxide Injected				
Canister 3 Preweight (g)	125.854	127.116	127.869	126.946
Canister 3 Postweight (g)	26.922	27.024	27.164	27.037
Canister 4 Preweight (g)	126.177	128.015	127.483	127.225
Canister 4 Postweight (g)	26.752	27.136	27.035	26.974
EtO Injected (lb)	0.44	0.44	0.44	0.44
Ethylene Oxide Exhausted				
EtO conc. (ppbv)	16	20	25	20
EtO emissions (lb/hr)	2.17E-05	2.72E-05	3.27E-05	2.72E-05
EtO emitted/cycle (lb)	2.77E-04	3.46E-04	4.16E-04	3.47E-04
Destruction Efficiency				
EtO DE (%)	99.9	99.9	99.9	99.9
Permit Limit (%)	-	-	-	*99.5*

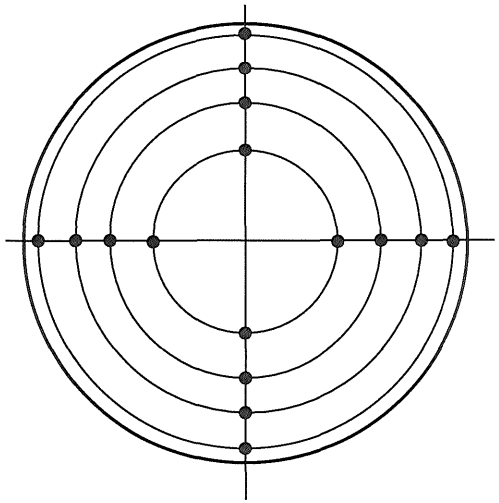
APPENDIX 1

- Sample Port Diagram

Impact Compliance and Testing, Inc.



Velocity sample locations as measured from stack wall



Pt. #	in.
1	0.50
2	0.63
3	1.16
4	1.93
5	4.06
6	4.84
7	5.37
8	5.5

2/11/21 ALR	**Beaumont Health – Royal Oak Sterilizer No. 7A & 8A Exhaust Sampling Location**		
	Scale None	Sheet 1 of 1	Impact Comp. & Testing Dwg. No. ETO-1